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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,811	04/29/2005	Jesus G Valenzuela	4239-67028-08	7353
36218 7590 08/03/2007 KLARQUIST SPARKMAN, LLP 121 S.W. SALMON STREET SUITE #1600 PORTLAND, OR 97204-2988				
			EXAMINER BASKAR, PADMAVATHI	
			ART UNIT 1645	PAPER NUMBER
			MAIL DATE 08/03/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/533,811	Applicant(s) VALENZUELA ET AL.	
	Examiner Padmavathi v. Baskar	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-38 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, Claims 1-6 and 23 (in part) drawn to substantially purified salivary Lu. longipalpis polypeptide and a composition comprising said polypeptide.

Further restriction to one SEQ.ID.NO required (see paragraph # 4).

Group II, Claims 7-18 and 24 (in part) are drawn to an isolated polynucleotide, recombinant expression vector, and host cell, an immunogenic composition DNA

Further restriction to one SEQ.ID.NO required (see paragraph # 4).

Group III Claims 19-22 (in part) drawn to an antibody

Further restriction to one SEQ.ID.NO required (see paragraph # 4).

Group IV Claims 25-30 (in part) drawn to a method for inducing an immune response

Further restriction to one SEQ.ID.NO required (see paragraph # 4).

Groups V Claim 31 (in part) drawn to a method for inhibiting a symptom of a Leishmania infection

Further restriction to one SEQ.ID.NO required (see paragraph # 4).

Group VI Claims 32 and 33 (in part) drawn to a method of manufacturing polypeptide as a medicament

Further restriction to one SEQ.ID.NO required (see paragraph # 4).

Group VII Claims 32 and 33 (in part) drawn to a method of manufacturing nucleic acid as a medicament

Further restriction to one SEQ.ID.NO required (see paragraph # 4).

Group VIII Claims 34-38 (in part) drawn to a method of diagnosing Leishmania infection using polypeptide

Further restriction to one SEQ.ID.NO required (see paragraph # 4).

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The inventions listed as Groups 1-VIII (in Part) do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

2. The technical feature of linking Groups I-VIII appears to be that they all relate to polynucleotide, polypeptide and antibody.

The technical feature of linking groups appears to be that they are all related to peptides, nucleic acids and antibodies and methods of using peptides, nucleic acids and antibodies.

However, Charlab R et al 1999 Proc Natl Acad Sci U S A. 1999 Dec 21; 96(26): 15155-60. disclose substantially purified salivary *L.longipalpis* polypeptide (see abstract and page 15157, left column) and thus read on group I. Therefore, the technical feature of linking groups I-VIII does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art and hence unity of invention is lacking.

The special technical feature of Group I considered to be polypeptide that shares no common structure, property and function with Group II since peptides contain amino acids and do not share the same or a corresponding technical feature with Group II nucleic acids.

The special technical feature of Group II is considered to be polynucleotide, which is made up of nucleic acids.

The special technical feature of Group III considered to be antibody that shares no common structure, property and function from Inventions I and II since it has an inherent affinity, avidity, and specificity that DNA or a simple protein is not capable of expressing and do not require each other for their practice.

The technical feature linking groups IV-VIII is considered to be methods utilizing products that share no common structure, property and function so as to form a single general inventive concept under Rule 13.1. Hence, unity is lacking among groups.

DISTINCT INVENTIONS

4. For each group of inventions I-VIII above, restriction to one of the following SEQ.ID.NO is also required under PCT Rule 13.1 because, under PCT Rule 13.2. Therefore, election is required of one of inventions I-VIII and one of SEQ.ID.NO: 3-68

Inventions SEQ.ID.NO: 1-68 are not so linked as to under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The claimed polypeptides and polynucleotides (i.e., SEQ.ID.NO 1-68) share no common special technical feature because the polynucleotides and peptides have no common structure (i.e., no common sequence) as evidenced by their sequences SEQ.ID.NO 1-68. These sequences that share no common

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structure as polynucleotides and polypeptides and are not linked by the same the same or a corresponding special technical feature so as to form a single general inventive concept. Therefore, where structural identity is required, such as for hybridization or expression of protein or binding of antibody, each sequence appears perform a different function in that peptides elicit an antibody response and nucleic acids encode peptides that specifically bind to an antibody. Thus they share no common structure and function so as to form a single general inventive concept under Rule 13.1. Hence, unity is lacking among groups SEQ.ID.NOS.

Applicant is required under PCT Rule 13.1 because, under PCT Rule 13.2 to elect a single disclosed SEQ.ID.NO from any group elected.

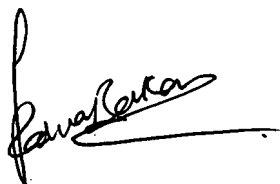
5. Applicant is required, in reply to this action, to elect a group and one sequence and identify the SEQ.ID.NO to which the claims shall be restricted. The reply must also identify the claims readable on the elected invention, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

6. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Right Fax number is 571-273-8300.


Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600



Padma Baskar Ph.D.


SUSAN UNGAR, PH.D
PRIMARY EXAMINER